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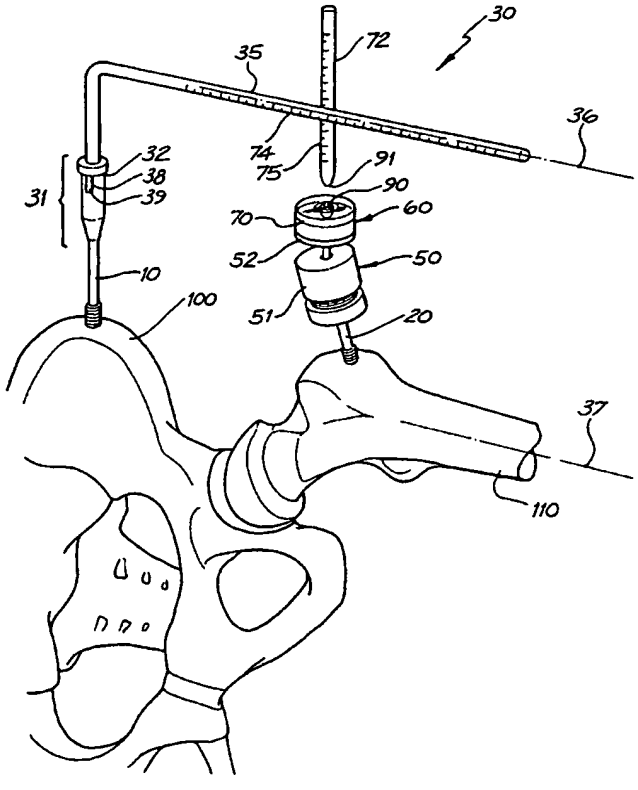
(54) Title: DEVICE FOR MEASURING LEG LENGTH



(57) Abstract: An apparatus (30) and method for using such apparatus to quantify the spatial relationship between two landmarks on two different objects which are moveably engaged. The apparatus and method have particular application in quantifying the spatial relationship between two rotatably engaged objects which are capable of moving (or being moved) about their engagement in any and all planes and are therefore useful in the performance of partial or total hip replacement procedures to ensure that the length of a patient's leg remains the same both prior to and following insertion of a prosthesis.

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DEVICE FOR MEASURING LEG LENGTH

Field of the Invention

The present invention relates to an apparatus, and method for using such apparatus, to quantify the spatial relationship between two landmarks on two different objects which are moveably engaged. More specifically, the present invention relates to an apparatus and method for making such quantification, where the two objects are rotatably engaged and capable of moving (or being moved) about their engagement in any and all planes. The apparatus and method of the present invention are particularly useful in the performance of partial or total hip replacement procedures, also known as arthroplasty. The apparatus and method can firstly be used to ensure that the length of a patient's leg remains the same both prior to and following insertion of a prosthesis. It can also be used to allow appropriate adjustment of leg length following insertion of a prosthesis.

Background Art

The following information is provided as background to the present invention and is not to be taken as representative of the common general knowledge in the art of the invention in Australia or elsewhere merely because of its inclusion in the present specification.

It is well known that there are many possible complications associated with hip arthroplasty, including infection, dislocation, loosening or breakage of components, unstable gait and/or general ambulatory difficulties, pain, discomfort, inequality of leg length, and sciatic nerve palsy, to name a few. Of these, it is noteworthy that "leg length inequality occurs frequently after total hip replacement and is a cause of patient dissatisfaction and/or litigation" (Huddleston H (1997) *An Accurate Method for measuring Hip Offset in Hip Arthroplasty* 20(4) Orthopedics 331-332).

For many years now, numerous alternative devices and methods have been employed for ensuring that leg length, both prior to and following insertion of a prosthesis, is unchanged. These have ranged from being simple to being fairly complicated.

At the simple end of the spectrum, for example, prior to dislocation of the hip, one end of a guidewire, Kirschner wire (K-wire) or Steinmann pin, is inserted into the ilium near the anterior superior iliac spine, and bent until its other end meets a point on the greater trochanter of the femur. The replacement prosthesis is then inserted and adapted until the greater

trochanter has returned to the position it was in at the end of the guidewire, K-wire or Steinmann pin, prior to dislocation of the hip (see, for example, the discussion in McGee H and Scott J (April 7 1983) *A Simple Method of Obtaining Equal Leg Length in Total Hip Arthroplasty*, Clinical Orthopaedics and Related Research 269-70).

In a slightly more involved process, a K-wire is inserted near the anterior superior iliac spine and one end of a suture is tied to an end of the K-wire and pulled taught until the other end of the suture meets a point on the greater trochanter of the femur. The length of the suture in this position is marked, dislocation of the hip and insertion of the prosthesis performed, and the prosthesis is then adapted until the greater trochanter has returned to the position it was in at the end of the suture prior to dislocation (see, for example, Maskovich R and Stuchin S (1986) *Accurate Determination of Limb Length During Total hip Arthroplasty* 46(1) Bulletin of the Hospital for Joint Diseases, 63-67).

Most, if not all, of the more complex methods and devices for confirming that leg length has not changed, also use reference points on the ilium and the femur for such confirmation. Examples of these include the "Three Pronged Iliac Reference Device with Adjustable Caliper" as described by Woolson and Harris (April 1985) in *A Method of Intraoperative Limb Length Measurement in Total Hip Arthroplasty* 194 Clinical Orthopaedics and Related Research, 207-210; the "Calipers Dual Pin Retractor" developed by Kobe Steel Ltd, Kobe Japan and described by Itokazu *et al.* (1997) in *A Simple Method of Intraoperative Limb Length Measurement in Total Hip Arthroplasty* 56(4) Hospital for Joint Diseases, 204-205; the "Femoral Caliper" designed by the Belfast Hip Group and described by O'Brian *et al.* (1996) in *Assessing the Accuracy of Femoral Component Placement in Custom Cemented Hip Replacement* 15(4) Orthopaedic Nursing, 47-53; the "Apparatus for Simplifying Total Hip Arthroplasty" (see US 5755794); and the "Hip Calibration Gauge" available from Enztec Limited, Unit 4, 45 Sonter Road, Sockburn, Christchurch, New Zealand.

Each of these techniques have had varying degrees of success in terms of accuracy. In some cases, radiographic techniques have been used in addition to the methods and devices just described in order to ensure better results. In fact, the use of medical imaging to confirm leg length has also been employed on its own, as the only means for confirmation that leg length

has not changed. For example, see the discussions in Farill J (1953) *Orthoradiographic Measurement of Shortening of the Lower Extremity* 2&3 (29) Medical Radiography and Photography, 31-38; Williamson J and Reckling F (1978) *Limb Length Discrepancy and Related Problems Following Total Hip Joint Replacement* 134 Clinical Orthopaedics and Related Research, 135-138; and Lindgren J and Rysavy J (1992) *Restoration of Femoral Offset during Hip Replacement* 63(4) Acta Orthop Scand, 407-410. The radiographic techniques described in those publications allow two-dimensional views only. In practical terms, this means that if there is any variation of movement between the ilium and the femur in the third dimension, including rotational movement, it may not be noted by examination of the films.

The fact that the femur is moveably engaged with the acetabulum in such a way that one can move in a number of different planes with respect to the other provides an important reason why many of the devices so far described have not been capable of very accurate results. In addition, the fact that following dislocation, the femur could be unintentionally slightly rotated prior to insertion of the replacement prosthesis, further adds to the difficulty in using the methods and devices so far described to ensure that leg length remains unchanged.

US 4872268 uses a different mechanism to the devices described above. This mechanism helps to determine the "relative disposition of limbs relative to posture" (column 1, lines 31-32). The invention discloses the use of a number of components including two arms, two rods, a scale ruler, two spirit levels and a gravitational goniometer. Once constructed according to the invention, it is capable of determining the relative dispositions of the limbs to the body. However, this device was developed in order to assist the process of ensuring that an amputee's prosthetic limb has the same relationship to his/her body as does the contralateral limb. Not only is it cumbersome, but some of its componentry would not have a use during a hip replacement procedure.

Nevertheless, the use of spirit levels provides the invention with a mechanism for addressing all three dimensional movements of the limbs with respect to their engagement at the limb girdles.

Another device which uses the assistance of a spirit level is that disclosed by US 5122145. Unlike US 4872268, this device was specifically designed for use in hip replacement procedures. At the beginning of the

procedure, an assistant is required to move the patient's leg into a readily reproducible position. According to some embodiments of the invention, a spirit level is placed on a measuring arm which extends from an engagement with two Steinmann pins in the ilium to an engagement with one Steinmann pin in the femur. Once the spirit level confirms that the measuring arm is level, measurements are taken from the measuring arm and from between the measuring arm and the femur. The replacement prosthesis is then inserted and adapted until it corresponds to an appropriate size according to the measurements taken.

The difficulty with this device is that it requires the assistant maintaining the femur in the initial position, to be able to reproduce that position at any time without reference to any particular guide. Accuracy of the determination of leg length therefore requires the assistant to be accurate in relocating the initial position. Even minor differences in the repositioning of the femur, including for example, slight rotation, will affect the accuracy of the device.

The present invention is directed to providing an alternative and improvement to the existing techniques and apparatus for use in the performance of hip replacement procedures.

Description of the Invention

In a first aspect, the present invention is a device for quantifying a spatial relationship between a first landmark on a first object and a second landmark on a second object, wherein the first object and the second object are moveably engaged, the device comprising:

(a) a first member and a second member;

(b) a level confirmation means comprising:

a level determining means; and

a level fixation means, the level fixation means having a body and at least one portion having a levelling surface moveable relative to the body, said moveable portion being securable to the body in a plurality of positions;

wherein the body of the level fixation means is connected to, or engageable with, the second member, and the level determining means is connected to, or engageable with, the moveable portion of the level fixation means; and

(c) a biaxial measuring means comprising:

a first measuring member having a measuring portion with a longitudinal axis; and

a second measuring member having a measuring portion with a longitudinal axis;

wherein the first measuring member is connected to, or engageable with, the second measuring member, and an engagement portion of the biaxial measuring means is connected to, or engageable with, the first member.

In a preferred embodiment, the first landmark and the second landmark are allocated to respective positions on a first object and a second different object. In some preferred embodiments, however, the two objects upon which the two landmarks are respectively allocated are, themselves, two different, but moveably engaged, portions of the same object. Two portions of bone surrounding an osteotomy site provide an example of two different, but moveably engaged, portions of the same object to which a device according to the present invention may be applied.

The present device may be used to quantify the spatial relationship between two landmarks on any two objects which are moveably engaged. It is, however, particularly valuable for quantifying such a relationship where the two objects are rotatably engaged, and capable of moving (or being moved) about their engagement in any and all planes. While the ball and socket joint of a hip does not provide such a vast range of movement, it does provide an example of a situation in which two objects - the acetabulum and the head of the femur - are rotatably engaged and are capable of moving (or being moved) about their engagement in a wide variety of planes.

The device of the present invention is especially useful during partial or total hip replacement procedures, because it allows intraoperative quantification of the spatial relationship between a landmark on the ilium and a landmark on the femur both prior to and following insertion of a prosthesis. Provided that throughout the procedure it is possible to bring the leg and the hip into the position they were in when the procedure began, affirmation that the spatial relationship between the landmark on the ilium and the landmark on the femur is the same before and after prosthesis insertion confirms that following the procedure, the length of the patient's leg will be the same as it was prior to the procedure, unless in fact a change in leg length is desired. The present invention provides the surgeon with an

opportunity, during the operation and before closure of the operative wound, to ensure that there is no discrepancy between the length of the patient's leg prior to and following insertion of the replacement prosthesis, unless it is so desired.

According to a second aspect, the present invention is a device for use in partial or total hip replacement procedures to quantify a spatial relationship between a first landmark on the ilium and a second landmark on the femur, the device comprising:

(a) a first member adapted to provide a landmark on the ilium, and a second member adapted to provide a landmark on the femur;

(b) a level confirmation means comprising:

a level determining means; and

a level fixation means, the level fixation means having a body and at least one portion having a levelling surface moveable relative to the body, said moveable portion being securable to the body in a plurality of positions;

wherein the body of the level fixation means is connected to, or engageable with, the second member, and the level determining means is connected to, or engageable with, the moveable portion of the level fixation means; and

(c) a biaxial measuring means comprising:

a first measuring member having a measuring portion with a longitudinal axis; and

a second measuring member having a measuring portion with a longitudinal axis;

wherein the first measuring member is connected to, or engageable with, the second measuring member, and an engagement portion of the biaxial measuring means is connected to, or engageable with, the first member.

In a preferred embodiment, the first member has a first end which is adapted to be inserted into the first object (ie. the ilium in hip replacement procedures), and a second end which is adapted to engage with the biaxial measuring means. The second member can have a first end which is adapted to be inserted into the second object (ie. the femur in hip replacement procedures) and a second end which is adapted to connect to, or engage with, the body of the level fixation means.

In a third aspect, the present invention consists in a method for confirming intraoperatively that the length of a patient's leg following a partial or total hip replacement is a desirable length, using a device according to the present invention, the method comprising the steps of:

(a) adjusting and securing the patient's pelvis in an appropriate position for the performance of a partial or total hip replacement procedure;

(b) moving the patient's leg into a readily reproducible position, and maintaining the leg in that position;

(c) advancing the first end of the first member into a location on the ilium proximate the anterior superior iliac spine on the appropriate side of the patient such that the second end of the first member protrudes from the ilium;

(d) advancing the first end of the second member into a location proximate the greater trochanter of the femur on the appropriate side of the patient such that the second end of the second member protrudes from the femur;

(e) assembling the level confirmation means by connecting or engaging the body of the level fixation means with the second end of the second member, and connecting or engaging the level determining means with the moveable portion of the level fixation means;

(f) with the patient's leg in the same position as attained in step (b), manipulating the moveable portion of the level fixation means until the level determining means indicates that the levelling surface of the moveable portion is level;

(g) securing the moveable portion of the level fixation means to the body of the level fixation means in the position in which the levelling surface of the moveable portion is level;

(h) engaging or connecting the engagement portion of the biaxial measuring means with the second end of the first member, and adjusting the first measuring member such that the longitudinal axis of the measuring portion of the first measuring member is parallel to a longitudinal axis of the patient's leg;

(i) slideably, or otherwise, engaging or connecting the second measuring member with the first measuring member, and/or positioning the biaxial measuring means, such that the longitudinal axis of the measuring portion of the second measuring member is in a perpendicular plane to that

of the longitudinal axis of the measuring portion of the first measuring member;

(j) moving the first and second measuring members in relation to one another or adjusting the biaxial measuring means, in order to take measurements determinative of a reproducible position on the level determining means.

(k) removing the biaxial measuring means and the level confirmation means without affecting the secured position of the moveable portion of the level fixation means;

(l) removing appropriate portions of bone, and other bodily tissues as necessary;

(m) placing a replacement prosthesis in an appropriate position;

(n) reassembling the level confirmation means, and causing the patient's leg to attain the readily reproducible position from step (b) by manipulating the leg until the level determining means indicates that the levelling surface is level, at which position the levelling surface was fixed in steps (f) and (g);

(o) reassembling the biaxial measuring means;

(p) modifying or replacing the replacement prosthesis as many times as necessary until the first end of the second measuring member abuts the reproducible position on the level determining means from step (j), thereby confirming that the length of the patient's leg both prior to and following insertion of the replacement prosthesis has not changed, or that the length of the patient's leg has changed to a desirable length;

(q) securing the prosthesis, removing all components of the device according to this invention, and completing the procedure.

In performing the above method, it will be appreciated that steps (b) to (e) could be performed in any order. In a further embodiment, the first and second members can be advanced into holes already formed in the ilium and femur, respectively. In a further embodiment, the taking of measurements in step (j) can include taking measurements from each of the measuring portions of the first and second measuring members.

In a preferred embodiment, the patient is positioned in the lateral position for the purpose of carrying out the procedure. In an alternative embodiment, however, the patient may be positioned in any other way which

is convenient and which would be advantageous to carrying out the procedure effectively.

In general terms, in the present invention, the spatial relationship between two landmarks, each on different objects which are moveably engaged (eg. the ilium and the femur), can be quantified with reference to three different but related measurements:

(i) a measurement in a first plane;

(ii) a measurement in a second plane which is perpendicular to the first plane; and

(iii) a level measurement which confirms, at any point in time, that the spatial orientations of the first plane and the second plane have not changed with respect to one another, and with respect to the spatial orientation they were in at the time when measurements in those planes were initially taken.

As disclosed above, many of the components of the device can be "connected to, or engageable with," one another or specific parts of one another. In certain preferred embodiments, it is to be understood that "connected to" may encompass "integral with".

In an alternative aspect, the present invention can comprise the method defined above with step (e) omitted. In this aspect, the body of the level fixation means is integral with the second end of the second member, and the level determining means is integral with the moveable portion of the level fixation means. In such an aspect, it is to be understood that in step (d), the level fixation means and level determining means are mounted to the second member on insertion of the second member into the femur.

In a still further alternative aspect, the present invention can comprise the method defined above with step (e) modified to the extent necessary where two or more of the components of the level confirmation means are already formed integrally with one another. In such a case, it can also be envisaged that the assembly of step (e) may have been performed prior to use of the device in the method. Consequently, when using a device according to such an embodiment, where two or more of these components are integral with one another, only the relevant parts (if any) of step (e) will need to be carried out.

In one preferred embodiment, the first measuring member and the second measuring member of the biaxial measuring means are individual

components wherein the first measuring member is an elongate structure with a substantially L-shape and the second measuring member is a substantially straight or straight elongate structure. Preferably, the engagement portion of the biaxial measuring means is located on a first arm of the L-shaped measuring member, the first arm projecting, when the device is in use, towards a central axis of a patient's body.

In another embodiment, the first measuring member and the second measuring member can be integral with one another. In this case, the biaxial measuring means is an elongate structure with an L-shape, wherein the second measuring member forms a first arm of the L-shape, and the first measuring member forms a second arm of the L-shape. The engagement portion of this embodiment of the biaxial measuring means is located on the end of the second measuring member which is not connected to that of the first measuring member. In a further embodiment, however, the engagement portion of the biaxial measuring means can be located on the end of the first measuring member which is not connected to that of the second measuring member.

A further preferred feature of the biaxial measuring means, is that the second measuring member has a telescopic structure, such that its length can be varied. The telescopic structure may be limited to the second measuring member alone, however, it may also extend into the engagement of the biaxial measuring means with the first member. The first measuring member may also be telescopic.

Where the first measuring member and the second measuring member are integral with one another, there is no requirement to "slideably engage or connect" the two measuring members as disclosed in step (i) of the third aspect. In this case, it will only be necessary to "position the biaxial measuring means" appropriately as disclosed as being the alternative in step (i).

In a preferred embodiment, the first and second members are respectively allocated to, and therefore, respectively designate two relevant landmarks, each on their own respective objects. The first end of each member is adapted to be inserted into the object upon which the relevant landmark has been allocated. At least a portion of the length of each member can be threaded. Where a thread is present, the pitch of the thread may be constant, or may vary along its length. In an alternative embodiment,

however, each first end can be smooth and, consequently, the respective members do not rely on a thread in order to advance into the respective objects. A distal tip of the first end of each member may be sharp and pointed. In an alternative embodiment, the distal tips can be smooth.

While in one embodiment, the first ends of both members can have different constructions, for the sake of simplicity, the first ends of both members can have the same construction. Furthermore, the first ends may be constructed in any way, shape or form which adequately adapts them for insertion into the objects upon which they should allocate a landmark.

Although the first end of each member may have the same construction, the second end of the first member provides a different purpose to the second end of the second member. The second ends are, therefore, preferably constructed differently to one another.

As disclosed above, the second end of the first member can be adapted to engage the engagement portion of the biaxial measuring means. In such an embodiment, while a plurality of mechanisms may be employed to enable such engagement, one mechanism for achieving engagement is to have at least a portion of the second end of the first member adapted to be inserted into the engagement portion of the biaxial measuring means. In another embodiment, the reverse may also be appropriate. In one preferred embodiment, a receptacle having a shape which complements the shape of the engagement portion which it is to receive is formed within the second end of the first member.

Although any shape can be formed, both the engagement portion and, consequently, the receptacle in the first member can have a component of their shape which is cylindrical. This provides a mechanism whereby, once engaged, the biaxial measuring means can be rotated about its engagement with the first member, until the longitudinal axis of its first measuring member is parallel to a longitudinal axis of the patient's leg. As disclosed by the third aspect, the ability to render these two longitudinal axes parallel to one another is of importance in the quantification of the spatial relationship between a landmark on the ilium and a landmark on the femur.

As it is preferable that once engaged with the first member, the biaxial measuring means be maintainable in an orientation where the longitudinal axis of its first measuring member is parallel to the longitudinal axis of the patient's leg, it is further preferable that the shape of the receptacle be such

that it does, in fact, maintain the biaxial measuring means in that orientation. In order to be capable of maintaining the first measuring member in the orientation just described, (and, therefore, to prevent the biaxial measuring means from rotating once the longitudinal axis of its first measuring member is in the desired orientation) the receptacle should be asymmetrical and, therefore, further comprise an additional slot which renders a transverse-section of the receptacle non-circular. For example, the additional slot may be in the shape of a rectangular prism which has a greater length than that of the diameter of the cylinder, and which is formed in line with the diameter of the cylinder. Such a slot, or a slot of any other shape, would, of course, represent a complementary shape to that of the shape formed on the engagement portion of the biaxial measuring means. Note that, where the engagement portion of the biaxial measuring means does have such an additional shape, namely a rectangular prism or other shape superimposed on a cylinder, the rectangular prism should be located proximal to a distal tip of the engagement portion. Such a location for the additional shape leaves a more distal portion of the engagement portion cylindrical in shape. The biaxial measuring means is, therefore, rotatable in the receptacle of the first member, until such time as it is advanced to an extent that the additional shape of the engagement portion is engaged with and advances into its complementary portion in the receptacle.

Where the second end of the first member has a part-cylindrical, part-asymmetrical, receptacle formed therein, an additional advantage provided by such a construction is that it provides an additional means to propel the first member into the object. A tool, having a complementary shape to that of the receptacle and/or the same shape as that of the engagement portion of the biaxial measuring means, is capable of providing such a means to propel the first member into the object. If there was no asymmetry in the cross-section of the receptacle, ie the receptacle was cylindrical only, a different tool, similar to a pair of pliers, would have to be used to grip the first member for screwing into the object.

The second end of the second member provides a different function and can be constructed differently. In one embodiment, the second end of the second member is adapted to engage the body of the level fixation means. Since the second member is preferably inserted into the second object, its second end is also adapted to be gripped by, for example, a tool like a pair of

pliers, or, more preferably, to receive the head of a screwdriver, Philips head screwdriver, Allen Key, or the like. An underside of the second end can have bone or tissue engaging means. The engaging means can comprise a plurality of protrusions that are forced into the bone an/or tissue on placement of the second member. The protrusions serve to assist in ensuring that the second member does not inadvertently move during use of the device.

A discussion of the second end of the second member requires some reference to the level fixation means. Once the levelling surface of the moveable portion of the level fixation means is level, the moveable portion itself can be secured to the body of the level fixation means in any one of a plurality of positions. In practical terms, this means that although the levelling surface is level, an axis of the moveable portion may be in any one of a number of different planes, relative to an axis of the body. As already indicated, it is important that the moveable portion be secured in this position: at a later stage during say, a partial or total hip replacement procedure, the fact that the moveable portion has remained in the position that its levelling surface is level, helps to ensure that the spatial relationship between a landmark on the ilium and a landmark on the femur is the same as when the procedure began, unless otherwise desired.

In other words, the second end of the second member is preferably adapted so that once engaged with the body of the level fixation means, the body of the level fixation means can be fixed in the position in which the levelling surface of its moveable portion has been determined as being level. During a hip replacement procedure according to this invention, the patient's pelvis is preferably secured; the patient's leg is preferably moved into a readily reproducible position; and the moveable portion of the level fixation means is preferably fixed to the body of the level fixation means. Thus, the only remaining movement between the body of the level fixation means and the second end of the second member which their engagement must prevent, is rotation of one with respect to the other. Accordingly, the adaptation at the second end of second engagement member for engaging the body of the level fixation means has a number of alternative embodiments.

For example, if the body of the level fixation means has a construction which is cylindrical, then the second end of the second member will have a complementary and corresponding cylindrical receptacle. In order to avoid any rotational movement between the two components once engaged, an

orifice or indent, capable of receiving a complementary protrusion, can be formed at the second end of the second member. The location where the orifice or indent is preferably not formed, is at the centre of the cylinder, as an orifice or indent in this location is unlikely to prevent rotation. The complementary protrusion is preferably formed at a corresponding position on the body of the level fixation means.

In an alternative embodiment, however, the receptacle formed in the second end of the second member can have an asymmetrical shape; or a symmetrical shape which prevents at least a corresponding and complementary portion of the body of the level fixation means from rotating once engaged with the second member. A symmetrical shape capable of preventing such rotation includes, but is not limited to, a hexagonal prism, a cube, a rectangular prism, and a triangular prism, etc.

As with the engagement between the engagement portion of the biaxial measuring means and the second end of the first member, the engagement between the body of the level fixation means and the second end of the second member may also be reversed. That is, rather than the second end of the second member being adapted to receive, into a receptacle, the body of the level fixation means, it can be adapted to have a protrusion which can be advanced into a corresponding and complementary receptacle in the body of the level fixation means.

The level confirmation means can be comprised of two components, namely the level fixation means and the level determining means. In one embodiment, the level fixation means and the level determining means are two separate components of the invention. In another embodiment, the level determining means may be integral with the moveable portion of the level fixation means.

The level fixation means can have a body and at least one moveable portion with a levelling surface, said moveable portion being securable to the body in a plurality of positions. The level fixation means is preferably constructed such that once engaged with the second member, the levelling surface essentially always faces away from the second object. The ability to move the moveable portion in a plurality of positions provides a mechanism to allow at least the levelling surface of the moveable portion to be moved into an orientation which is level, as determined by the level determining means. While the moveable portion can be one individual component of the

level fixation means, the body of the level fixation means can be comprised of two separate, but threadedly engageable, components. Such a body provides a mechanism to secure the moveable portion to the body in a particular position.

In a preferred embodiment, the moveable portion has a platform member upon which resides the levelling surface. The levelling surface is preferably planar. In an alternative embodiment, the levelling surface may undulate or may have any other surface characteristic which complements the ability of the level determining means to determine that the levelling surface is level. The platform member may have any cross-sectional shape with any particular size, though a circular shape no larger in diameter than about 3-6cm is preferred. It may further be of any thickness. However, in preferred embodiments, the thickness of the platform member is kept to a minimum in order to ensure that the size of the level fixation means is not cumbersome.

A rod can connect to, or be integrally formed with, a spherical member and extend to a substantially central position on the opposite side of the platform member to that of the levelling surface. The spherical member may be a full sphere or a section of sphere. The spherical member of the moveable portion is preferably substantially or wholly housed by the body of the level fixation means.

As explained above, the body of the level fixation means can be comprised of two different, but threadedly engageable, components: a base member and a cap member.

The base member is preferably a solid, substantially cylindrical, structure with a thread which extends along its length. One end of the base member is adapted to connect to or engage with the second end of the second member. The other end of the base member is deemed the seat end because it provides a seating surface for the spherical member of the moveable portion. The seating surface is formed as a dimple or dent in the surface of the seat end of the base member. The dimple or dent provides a spherical surface which complements the shape of the spherical member.

The cap member is preferably comprised of a crown with a central orifice and a skirt portion which extends from an outer perimeter of the crown. An inner surface of the skirt portion is threaded so that the cap member can engage the base member.

In a preferred embodiment, the level fixation means is constructed as follows: the rod of the moveable portion passes through the orifice in the crown of the cap member, such that the platform member remains on the outside of the cap member, while the spherical member is substantially housed by the skirt portion of the cap member; the base portion with its seat end facing the spherical member is then brought into threaded engagement with the skirt portion of the cap member. Consequently, the spherical member of the moveable portion of the level fixation means is housed by the body of the level fixation means. In practical terms, this construction provides a mechanism by which the moveable portion can move through a plurality of positions, while its spherical member rotates about a contact with the seat formed on the seat end of the base member.

Once the levelling surface of the platform member is determined to be level by the level determining means, the cap member can be advanced into greater and greater engagement with the base member. Such advance causes a distance between the crown of the cap member and the seat end of the base member to diminish. Ultimately, the distance between the crown and the seat end will be so small that the spherical member is held tightly against the seating surface, and unable to move. The moveable portion is, therefore, secured in the desired position.

In a preferred embodiment, the desired position for securing the moveable portion of the level fixation means is determined with reference to the level determining means.

A preferred feature of a level determining means according to the invention is that it is capable of indicating when the levelling surface of the level fixation means is level in all horizontal planes simultaneously. Accordingly, the level determining means can be circular spirit level (a bulls-eye spirit level). In an alternative embodiments, the level determining means can comprise at least two single-plane spirit levels in direct communication with one another, and crossing over each other at an angle. Where only two such single-plane spirit levels are used, the preferred angle is 90 degrees.

Like the levelling surface, the level determining means can be of any cross-sectional shape and size, however, a round shape having a diameter of no greater than about 3-6cm is preferable. In most embodiments, it is most preferable for the cross-sectional shape and size of the spirit level to accord with those of the levelling surface. In an alternative embodiment, the level

determining means may only engage the levelling surface on one part of the levelling surface, in which case there is no need for its cross-sectional shape and size to accord with those of the levelling surface.

The spirit level can have at least a portion which is adapted to connect to or engage with the levelling surface of the moveable portion of the level fixation means. In one embodiment, a surface of the spirit level has complementary surface characteristics to that of the levelling surface. Both of these surfaces are, as indicated above, most preferably planar. In one case, a short skirt member can extend around the perimeter of the portion of the level determining means which connects to or engages with the levelling surface of the level fixation means. The skirt provides one mechanism to maintain engagement between these components. In another embodiment, a protrusion can extend downwardly from a lower edge of the level determining means. The protrusion can be received in an orifice formed in the levelling surface. Engagement of the protrusion in the orifice can act to prevent rotation of the level determining means relative to the levelling surface and also ensures that it is returned to the same position if removed.

The present invention envisages that the level determining means may be manufactured such that it is disposable. However, there is no limitation on the type of level determining means which can be used in carrying out this invention. Indeed, in one embodiment the level determining means can be a digital spirit level.

In a further preferred embodiment, the spirit level, or other form of level determining means, is integral with the moveable portion of the level fixation means. In these cases, there is, of course, neither a requirement for a mechanism to maintain engagement between the level determining means and levelling surface, nor, for that matter, any need to assemble or reassemble the level confirmation means in accordance with steps (e) and (n) of the third aspect of the invention.

Once the levelling surface has been confirmed as being level by the level determining means and fixed in that orientation, the biaxial measuring means is employed in order to provide two further variables for quantifying the spatial relationship between the two landmarks. As disclosed above, the biaxial measuring means has an engagement portion for engaging the first member, and is further preferably comprised of a first measuring member and a second measuring member.

The engagement portion of the biaxial measuring means is preferably adapted to engage the second end of the first member. The engagement portion, depending on the construction of the biaxial measuring means, may be located on either the first measuring member or the second measuring member, or there may be an engagement portion on both measuring members so that the biaxial measuring means can be engaged from either side.

In addition, since one embodiment where the first measuring member and the second measuring member are integral with one another has already been described, the following discussion will focus on an embodiment of these two measuring members where they are both individual components of the invention.

In a further embodiment, the second measuring member is a straight elongate structure, while the first measuring member is an elongate structure with an L-shape, wherein a first end of the measuring member forms at least a part of the first arm of the L-shape, and the measuring portion forms at least a part of the second arm of the L-shape. The L-shape renders it possible to have the first end projecting toward a central axis of the patient's body in which orientation it can engage (via the engagement portion of the biaxial measuring means) with the first member, while the longitudinal axis of the measuring portion is projecting parallel to a longitudinal axis of the patient's leg. In a further embodiment, any other shape for the first measuring member which allows it to adopt both of these axes simultaneously is appropriate. In an alternative embodiment, other axes may be used to take measurements and, consequently, other shapes will be more appropriate for the first measuring member.

One or both of the measuring portions of the second measuring member and the first measuring member can be calibrated along at least a portion of their respective lengths with a measuring scale. The calibrations may extend along the entire length of the measuring portion and along the entire length of the measuring member. There may be more than one length of calibration along the entire length of the measuring member. For example, in embodiments, where the first measuring member is L-shaped, there may be one length of calibration along one arm of the L-shape, and a second length of calibration along the second arm or measuring portion of the L-shape. In an alternative embodiment, a measuring scale can be provided on the upper surface of the level determining means. The measuring scale can

be provided in addition to or instead of the calibrated measuring scale on the measuring portion of the second measuring member.

The measurement obtained from the measuring portions of the measuring members and/or the scale on the level determining means need not have any specific units. That is to say, that provided the units of measurement do not change and the measurements recorded at one time are the same as the measurements recorded at another time, application of a device according to this invention will still successfully quantify a spatial relationship between two landmarks on two moveably engaged objects.

In an alternative embodiment, no calibrations are present on either of the measuring portions of either measuring member. In this embodiment, measurements may be taken by any one of a plurality of electronic devices capable of determining the lengths of the relevant portions. For example, a pen with an electronic nib, which when run along the length of an object will display a measurement of the length the nib has moved.

In a still further alternative embodiment, other techniques may be applied to the measuring portions to provide measurements which reflect a value representative of the relevant lengths of the measuring portions. Devices which use ultrasound, infra-red, or laser-based systems and the like fall within the category of devices applicable to such techniques.

In embodiments in which the first measuring member and the second measuring member are not integral with one another, each or both are adapted to connect to, or engage with one another. In one such embodiment, a longitudinal slot is provided along the length of the measuring portion of one or the other of the measuring members, said slot being slideably engageable with one or the other measuring member.

According to such an embodiment, it is preferred that the second measuring member have such a slot and also have the engagement portion of the biaxial measuring means on one of its ends. In this particular embodiment, the first measuring member is not L-shaped, but is also simply a straight elongate member. In this case, the second measuring member is initially engaged with the second end of the first member, and the first measuring member is then slideably engaged in the slot of the second member. The engagement between the measuring members of this embodiment should be such that, as with all other embodiments, the longitudinal axis of the measuring portion of the first measuring member is

able to be positioned parallel to a long axis of the leg. The engagement should additionally be such, as with all other embodiments, that the longitudinal axis of the measuring portion of the second measuring member is able to be positioned in a plane perpendicular to the lie of the plane of the measuring portion of the first measuring member.

In yet a further embodiment wherein the two measuring members are individual components of the device, a measuring member engagement means may be used to engage the measuring members for operation. The measuring member engagement means according to such embodiments is preferably connected to, or engageable with, the first measuring member and/or the second measuring member, in order to be capable of slideably engaging one with the other. In a preferred embodiment, a measuring member engagement means comprises an elongate member having two orifices through which each measuring member can pass. In an alternative embodiment, the measuring member engagement means can be constructed in any way, shape or form, which renders it capable of engaging the two measuring members in the appropriate orientation.

A preferred feature of a measuring member engagement means, is that it further comprises a means for restricting the measuring members from continuing to slide. For example, in one preferred embodiment, a screw member could be used to tighten each measuring member in its respective desired position within the measuring member engagement means.

As disclosed by step (j) in the third aspect of the invention, it is important that the measuring members be able to move in relation to one another, so that appropriate and related measurements can be taken. In fact, in step (j) it is preferred that the first and second measuring members be moved (eg slid along their engagement with one another or the measuring member engagement means) in relation to one another, in order to take measurements from each of the measuring portions of the first and second measuring members, the measurements being directly related to a reproducible position on the level determining means.

A desirable reproducible position on the level determining means is the centre of the circular spirit level (the preferred level determining means). However, any other reproducible position on the level determining means will also be appropriate. Where the upper surface of the level determining

means has a measuring scale, the reproducible position can, for example, be any noted position along that scale.

Provided that the measurements taken from both measuring portions of respective measuring members are related to a reproducible position on the level determining means in accordance with this invention, then the spatial relationship between two landmarks on two moveably engaged objects can be successfully quantified. If those two landmarks define positions on the ilium and the femur respectively, and following insertion of a hip replacement prosthesis, the spatial relationship between them is the same as it was before the replacement prosthesis was inserted, then the length of the patient's leg will also remain the same.

Brief Description of the Drawings

By way of example, preferred embodiments of the invention are described with reference to the accompanying drawings in which:

Fig. 1 is a cross-sectional diagram of a first member according to a preferred embodiment of the invention;

Fig. 2 is a cross-sectional diagram of a second member according to a preferred embodiment of the invention;

Fig. 3a is an exploded perspective view of a level fixation means according to a preferred embodiment of the invention;

Fig. 3b is a cross-sectional diagram of the level fixation means of Fig. 3a with its components assembled;

Fig. 4 is a perspective view of a level determining means according to a preferred embodiment of the invention;

Fig. 5a is schematic diagram illustrating a preferred embodiment of a first measuring member according to the invention;

Fig. 5b is schematic diagram illustrating a preferred embodiment of a second measuring member according to the invention;

Fig. 5c is a cross-sectional diagram of a measuring member engagement means according to a preferred embodiment of the invention;

Fig. 6 is a perspective view of one embodiment of a biaxial measuring means according to the invention, wherein the first measuring member and the second measuring member are integral with one another; and

Fig. 7 is a simplified perspective view illustrating a preferred embodiment of the device being used to quantify the spatial relationship between a landmark on the ilium and a landmark on the femur of a patient.

Preferred Mode of Carrying Out the Invention

Although a device according to this invention can be used to quantify the spatial relationship between two landmarks on any two objects which are moveably engaged, the following discussion will describe the device with particular reference to its application in partial or total hip replacement procedures.

The first and second members 10, 20 are respectively allocated to, and therefore, respectively designate two relevant landmarks: the first 10 on the ilium 100, and the second 20 on the femur 110. The first end 15,16, respectively, of each member 10,20 is adapted to be inserted into the bone upon which the relevant landmark has been allocated. Accordingly, at least a portion 13,14, respectively, of the length of each member 10,20 is threaded. A distal tip 17,18, respectively, of the first end 15,16 of each member 10,20 is sharp and pointed.

Although the first end 15,16, respectively, of each member 10,20 may have the same construction, the second end 11 of the first member 10 provides a different purpose to the second end 12 of the second member 20. The second ends 11,12 are, therefore, preferably constructed differently to one another.

In the depicted embodiments, the second end 11 of the first member 10 is adapted to engage the engagement portion 31 of the biaxial measuring means 30. The mechanism for achieving engagement is to have the second end 11 of the first member 10 adapted to receive the engagement portion 31 of the biaxial measuring means 30. A receptacle 32 having a shape which complements the shape of the engagement portion 31 which it is to receive is formed within the second end 11 of the first member 10.

Although any shape can be formed, it is preferable that both the engagement portion 31 and, consequently, the receptacle 32 in the member 10 have corresponding cylindrical components 33,34. This provides a mechanism whereby, once engaged, the biaxial measuring means 30 can be rotated about its engagement with the first member 10, until the longitudinal axis 36 of its first measuring member 35 is parallel to a longitudinal axis 37 of the patient's leg.

In order to be capable of preventing the biaxial measuring means 30 from rotating once the longitudinal axis 36 of its first measuring member 35 is in the desired orientation, the receptacle 32 should be asymmetrical and,

therefore, further comprise an additional slot 38 which renders a transverse-section of the receptacle 32 non-circular. As shown in Fig. 1, the additional slot 38 has the shape of a rectangular prism which is formed in line with the diameter of the cylinder 34. Such a slot 38, represents a complementary shape to that of the shape of a complementary tag 39 formed on the engagement portion 31 of the biaxial measuring means 30. Note that the complementary tag 39 formed on the engagement portion 31 is located proximal a distal tip 40 of the engagement portion 31. Such a location leaves a more distal portion of the engagement portion 31 cylindrical in shape. The biaxial measuring means 30 is, therefore, rotatable in the receptacle 32 of the first member 10, until such time as it is advanced to an extent that the tag 39 of the engagement portion 31 is engaged with and advances into its complementary slot 38 in the receptacle 32.

The second end 12 of the second member 20 provides a different function and is constructed differently. In preferred embodiments, the second end 12 of the second member 20 is adapted to engage the body 51 of the level fixation means 50.

Since the second member 20 and the level fixation means 50 are closely related in the preferred mode of carrying out the invention, certain preferred features of one are now discussed with reference to the other.

The second end 12 of the second member 20 is preferably adapted so that once engaged with the body 51 of the level fixation means 50, the body 51 can be fixed in the position in which the levelling surface of its moveable portion 52 has been determined as being level. During a hip replacement procedure according to this invention, the patient's pelvis is preferably secured; the patient's leg is preferably moved into a readily reproducible position; and the moveable portion 52 of the level fixation means 50 is preferably fixed to the body 51 of the level fixation means 50.

Because the level fixation means is such that the moveable portion 52 can be fixed to the body 51 in any one of a plurality of positions, the adaptation at the second end 12 of second member 20 for engaging the body 51 of the level fixation means 50 must only be capable of preventing rotation between the two components 20,50. The second end 12 is, therefore, preferably formed with an orifice 41 capable of receiving a complementary protrusion 42 on the level fixation means 50.

The level confirmation means 60 of preferred embodiments is comprised of two components: the level fixation means 50 and the level determining means 70.

As illustrated in Figs. 3a and 3b, the level fixation means 50 can have a body 51 and at least one moveable portion 52 with a levelling surface 53. It is preferably constructed such that once engaged with the second member 20, the levelling surface 53 essentially always faces away from the femur 110.

The moveable portion 52 has a platform member 54 upon which resides the levelling surface 53. The levelling surface 53 is preferably planar and, preferably, has a circular shape no larger in diameter than about 3-6cm. A rod 55 is integrally formed with a spherical member 56 and extends to a substantially central position on the opposite side of the platform member 54 to that of the levelling surface 53.

The body 51 of the depicted level fixation means 50 is comprised of two different, but threadedly engageable, components: a base member 57 and a cap member 58.

The depicted base member 57 is a solid, substantially cylindrical, structure with a thread 59 which extends along its length. One end 61 of the base member is adapted to connect to or engage with the second end 12 of the second member 20. The other end, is the seat end 62 because it provides a seating surface 63 for the spherical member 56 of the moveable portion 52. The seating surface 63 is formed as a dimple or dent in the surface of the seat end 62 of the base member 57. The dimple or dent provides a spherical surface which complements the shape of the spherical member 56.

The depicted cap member 58 is comprised of a crown 64 with a central orifice 65 and a skirt portion 66 which extends from an outer perimeter of the crown 64. An inner surface of the skirt portion 66 is threaded so that the cap member 58 can engage the base member 57.

As illustrated by Figs. 3a and 3b, the level fixation means 50 is constructed as follows: the rod 55 of the moveable portion 52 passes through the orifice 65 in the crown 64 of the cap member 58, such that the platform member 54 remains on the outside of the cap member 58, while the spherical member 56 is substantially housed by the skirt portion 66 of the cap member 58; the base portion 57 with its seat end 62 facing the spherical member 56 is then brought into threaded engagement with the skirt portion 66 of the cap

member 58. Consequently, the spherical member 56 of the moveable portion 52 is housed by the body 51 of the level fixation means 50.

Once the levelling surface 53 of the platform member 54 is determined to be level by the level determining means 70, the cap member 58 can be advanced into greater and greater engagement with the base member 57. Such advance causes a distance between the crown 64 of the cap member 58 and the seat end 62 of the base member 57 to diminish. Ultimately, the distance between the crown 64 and the seat end 62 will be so small that the spherical member 56 is held tightly against the seating surface 63, and unable to move.

A preferred feature of a level determining means 70 according to the invention is that it is capable of indicating when the levelling surface of the level fixation means is level in all horizontal planes simultaneously. As illustrated by Fig. 4, the level determining means 70 can be a circular or bulls-eye spirit level. It is most preferable for the cross-sectional shape and size of the spirit level 70 to accord with those of the levelling surface 53.

The depicted bulls-eye spirit level 70 has at least a portion 71 which is adapted to connect to or engage with the levelling surface 53 of the moveable portion 52 of the level fixation means 50. A protrusion 101 can extend downwardly from a lower surface of the portion 71 and be engageable with a complementary orifice or slot (not depicted) in the levelling surface 53. The protrusion 101 serves to prevent rotation of the spirit level 70 and also ensures that it is returned to the same position when re-mounted on the levelling surface 53. As depicted, the upper surface of the spirit level 70 can also have a measuring scale 102. As depicted, the protrusion 101 and scale 102 are preferably aligned. On assembly, it is preferred that the spirit level 70 be positioned such that the scale is parallel with the longitudinal axis of the second arm of the first measuring member 35.

Once the levelling surface 53 has been confirmed as being level by the level determining means 70 and fixed in that orientation, the biaxial measuring means 30 is employed in order to provide two further variables for quantifying the spatial relationship between the two landmarks. As disclosed above, the biaxial measuring means 30 has an engagement portion 31 (already discussed in detail above) for engaging the first member 10, and is further preferably comprised of a first measuring member 35 and a second measuring member 72.

As depicted in Figs. 5a-5c, the second measuring member 72 is a straight elongate structure, while the first measuring member 35 is an elongate structure with an L-shape, wherein a first end 73 of the measuring member forms at least a part of the first arm of the L-shape, and the measuring portion 74 forms at least a part of the second arm of the L-shape. With reference to Fig. 7, it can be seen that the L-shape renders it possible to have the first end 73 projecting toward a central axis of the patient's body in which orientation it can engage (via the engagement portion 31 of the biaxial measuring means 30) with the first member 10, while the longitudinal axis 36 of the measuring portion 74 is projecting parallel to a longitudinal axis 37 of the patient's leg.

In the depicted embodiment, the measuring portions 75,74 of the second measuring member 72 and the first measuring member 35 are calibrated with a scale along at least a portion of their respective lengths. The measuring scale 74 can be used as an alternative to or together with the scale 102 provided on the upper surface of the spirit level 70.

In the preferred embodiment depicted by Figs. 5a-5c, the first measuring member 35 and the second measuring member 72 are not integral with one another, and a measuring member engagement means 80 is used to engage the measuring members 35,72 for operation. The measuring member engagement means 80 is preferably connected to, or engageable with, the first measuring member 35 and the second measuring member 72, in order to be capable of slideably engaging one with the another. It comprises an elongate member 81 having two orifices 82 through which each measuring member 35,72 can pass.

The measuring member engagement means 80 further comprises means for restricting the measuring members from continuing to slide. In the embodiment depicted in Fig. 5c, a screw member 83 is used to tighten each measuring member 35,72 in its respective desired position within the measuring member engagement means 80.

As disclosed by step (j) in the third aspect of the invention, it is important that the measuring members 35,72 be able to move in relation to one another, so that appropriate and related measurements can be taken. In fact, step (j) discloses that, preferably, the first and second measuring members 35, 72 should be moved (eg slid along their engagement with one another or the measuring member engagement means 80) in relation to one

another, in order to allow the taking of measurements determinative of a reproducible position 90 on the level determining means 70. As depicted in Fig. 4, a desirable reproducible position 90 on the level determining means is the centre of the bulls-eye spirit level. The reproducible position could, however, be a different noted position along scale 102.

Fig. 6 depicts another preferred embodiment of a biaxial measuring means according to this invention. In the illustrated embodiment, the first and second measuring members 35,72 are integral with one another. There is, therefore, no requirement for a measuring member engagement means 80 in this embodiment of the invention.

As can be seen, both measuring members 35,72 have a telescopic structure, which enables them to expand and contract as required. It is to be noted that the engaging portion 31 is located on an end of the second measuring member 72 in this particular embodiment. As already explained, there is, of course, no reason why the engaging portion 31 could not be located on the end of the first measuring member 35, (as is the case in the embodiment depicted in Fig. 5a). Furthermore, there could also be an engaging portion on the end of each measuring member 35,72 so that the biaxial measuring means 30 can be engaged with the first member 10 from either of the ends of the measuring members 35,72.

Fig. 7 illustrates the components of this invention as assembled after steps (a)-(j) from the third aspect of the invention have been carried out. For the sake of simplicity, the second measuring member 72 is depicted in a general working orientation rather than in engagement with the first measuring member 35 as described above. At this point, provided that the second end 91 of the second measuring member 72 points to and abuts the reproducible position 90 on the level determining means 70, then the spatial relationship between the landmark on the ilium 100 and the landmark on the femur 110 can be quantified by taking measurements from the first and second measuring members 35,72. Then, as disclosed by remaining steps (k)-(q), the device according to this invention is used as a guide to appropriately adapt the shape and size of a replacement prosthesis to ensure that the length of the patient's leg remains the same both prior to and following prosthetic insertion, unless a change of length is in fact desired.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in

the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

CLAIMS:

1. A device for quantifying a spatial relationship between a first landmark on a first object and a second landmark on a second object, wherein the first object and the second object are moveably engaged, the device comprising:

(a) a first member and a second member;

(b) a level confirmation means comprising:

a level determining means; and

a level fixation means, the level fixation means having a body and at least one portion having a levelling surface moveable relative to the body, said moveable portion being securable to the body in a plurality of positions;

wherein the body of the level fixation means is connected to, or engageable with, the second member, and the level determining means is connected to, or engageable with, the moveable portion of the level fixation means; and

(c) a biaxial measuring means comprising:

a first measuring member having a measuring portion with a longitudinal axis; and

a second measuring member having a measuring portion with a longitudinal axis;

wherein the first measuring member is connected to, or engageable with, the second measuring member, and an engagement portion of the biaxial measuring means is connected to, or engageable with, the first member.

2. The device of claim 1 wherein the first object and the second object are rotatably engaged and capable of moving about their engagement in any and all planes.

3. The device of claim 1 when used in partial or total hip replacement procedures.

4. The device of claim 3 wherein the first object is the ilium and the second object is the femur.

5. The device of any one of the preceding claims wherein the first member has a first end which is adapted to be inserted into the first object, and a second end which is adapted to engage the engagement portion of the biaxial measuring means.

6. The device of any one of the preceding claims wherein the second member has a first end which is adapted to be inserted into the second object and a second end which is adapted to engage the body of the level fixation means.

7. The device of claim 5 wherein the second end of the first member is adapted to receive the engagement portion of the biaxial measuring means.

8. The device of claim 7 wherein the second end of the first member includes a receptacle, the receptacle having a shape complementary to the shape of the engagement portion of the biaxial measuring means.

9. The device of claim 8 wherein both the engagement portion of the biaxial measuring means and the receptacle of the first member have a component which is cylindrical such that the engagement portion is rotatable within the receptacle.

10. The device of claim 8 or claim 9 wherein the receptacle further includes a slot which renders a transverse-section of a portion of the receptacle non-circular.

11. The device of claim 10 wherein the slot is a complementary shape to a shape formed on the engagement portion of the biaxial measuring means.

12. The device of claim 11 wherein when the shape formed on the engagement portion engages and advances into the slot, the first measuring means is held in a fixed position substantially parallel to the longitudinal axis of a patient's leg.

13. The device of claim 6 wherein the second end of the second member includes an orifice or an indent to receive a complementary structure of the body of the level fixation means thereby preventing any rotational movement between the second member and the body of the level fixation means.

14. The device of any one of the preceding claims wherein the moveable portion of the level fixation means includes a platform member upon which the levelling surface is positioned.

15. The device of claim 14 wherein the moveable portion further includes a spherical member connected to the platform member by a rod member.

16. The device of claim 15 wherein the spherical member is adapted to engage a complementary portion of the body of the level fixation means.

17. The device of any one of the preceding claims wherein the body of the level fixation means includes a cap member and a base member in threaded engagement with one another.

18. The device of claim 17 wherein the base member has a first end for engagement with the second end of the second member and a second end for engagement with the cap member.

19. The device of claim 18 wherein the second end of the base member includes a seating surface for the spherical member of the moveable portion.

20. The device of any one of claims 17 to 19 wherein the cap member includes a crown with a central orifice and a skirt portion which extends from an outer perimeter of the crown.

21. The device of claim 20 wherein an inner surface of the skirt portion is threaded.

22. The device of claim 20 or claim 21 wherein the central orifice of the crown is adapted to receive the rod member of the moveable portion such that the platform member is positioned on the outside of the cap member and the spherical member is positioned substantially within the skirt portion of the cap member.

23. The device of claim 22 wherein the cap member and the base member are capable of being brought into increasing threaded engagement such that the spherical member is caused to move toward the seating surface.

24. The device of claim 23 wherein upon determination that the levelling surface of the level fixation means is level, the cap member and the base member are capable of being brought into increasing threaded engagement such that the spherical member is held tightly against the seating member.

25. The device of any one of the preceding claims wherein the first and the second measuring members have a telescopic structure such that their length is variable.

26. The device of any one of the preceding claims wherein one or both of the measuring members are calibrated along at least a portion of their respective lengths with a measuring scale.

27. The device of any one of the preceding claims wherein the level determining means is a circular spirit level.

28. The device of claim 27 wherein a measuring scale is provided on an upper surface of the spirit level.

29. The device of claim 27 or claim 28 wherein the circular spirit level has at least a portion which is adapted to connect to or engage with the levelling surface of the moveable portion of the level fixation means.

30. A method for confirming intraoperatively that the length of a patient's leg following a partial or total hip replacement is a desirable length, using a device according to any one of the preceding claims, the method comprising the steps of:

(a) adjusting and securing the patient's pelvis in an appropriate position for the performance of a partial or total hip replacement procedure;

(b) moving the patient's leg into a readily reproducible position, and maintaining the leg in that position;

(c) advancing the first end of the first member into a location on the ilium proximate the anterior superior iliac spine on the appropriate side of the patient such that the second end of the first member protrudes from the ilium;

(d) advancing the first end of the second member into a location proximate the greater trochanter of the femur on the appropriate side of the patient such that the second end of the second member protrudes from the femur;

(e) assembling the level confirmation means by connecting or engaging the body of the level fixation means with the second end of the second member, and connecting or engaging the level determining means with the moveable portion of the level fixation means;

(f) with the patient's leg in the same position as attained in step (b), manipulating the moveable portion of the level fixation means until the level determining means indicates that the levelling surface of the moveable portion is level;

(g) securing the moveable portion of the level fixation means to the body of the level fixation means in the position in which the levelling surface of the moveable portion is level;

(h) engaging or connecting the engagement portion of the biaxial measuring means with the second end of the first member, and adjusting the first measuring member such that the longitudinal axis of the measuring portion of the first measuring member is parallel to a longitudinal axis of the patient's leg;

(i) slideably, or otherwise, engaging or connecting the second measuring member with the first measuring member, and/or positioning the biaxial measuring means, such that the longitudinal axis of the measuring portion of the second measuring member is in a perpendicular plane to that

of the longitudinal axis of the measuring portion of the first measuring member;

(j) moving the first and second measuring members in relation to one another or adjusting the biaxial measuring means, in order to take measurements determinative of a reproducible position on the level determining means.

(k) removing the biaxial measuring means and the level confirmation means without affecting the secured position of the moveable portion of the level fixation means;

(l) removing appropriate portions of bone, and other bodily tissues as necessary;

(m) placing a replacement prosthesis in an appropriate position;

(n) reassembling the level confirmation means, and causing the patient's leg to attain the readily reproducible position from step (b) by manipulating the leg until the level determining means indicates that the levelling surface is level, at which position the levelling surface was fixed in steps (f) and (g);

(o) reassembling the biaxial measuring means;

(p) modifying or replacing the replacement prosthesis as many times as necessary until the first end of the second measuring member abuts the reproducible position on the level determining means from step (j), thereby confirming that the length of the patient's leg both prior to and following insertion of the replacement prosthesis has not changed, or that the length of the patient's leg has changed to a desirable length;

(q) securing the prosthesis, removing all components of the device according to this invention and completing the procedure.

31. The method of claim 30 wherein the measuring portions of the second measuring member and the first measuring member are calibrated with a measuring scale along at least a portion of their respective lengths.

32. The method of claim 30 or claim 31 wherein the level determining means is a circular spirit level and the reproducible position defined in step (j) is the centre of the circular spirit level.

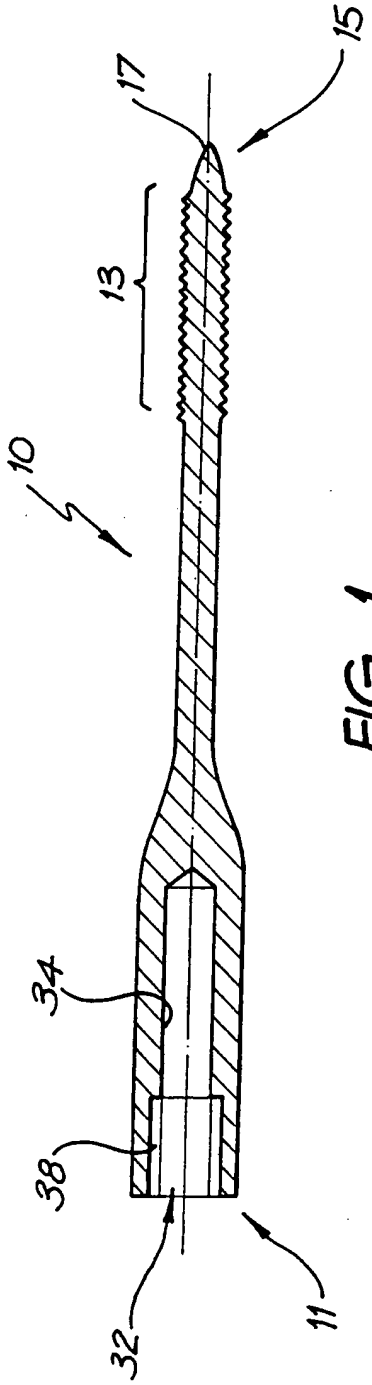

FIG. 1

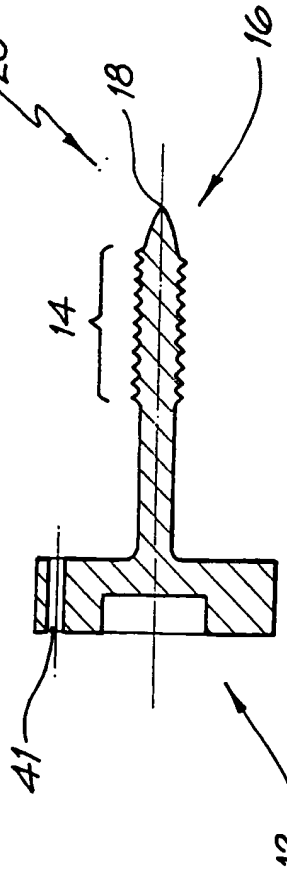

FIG. 2

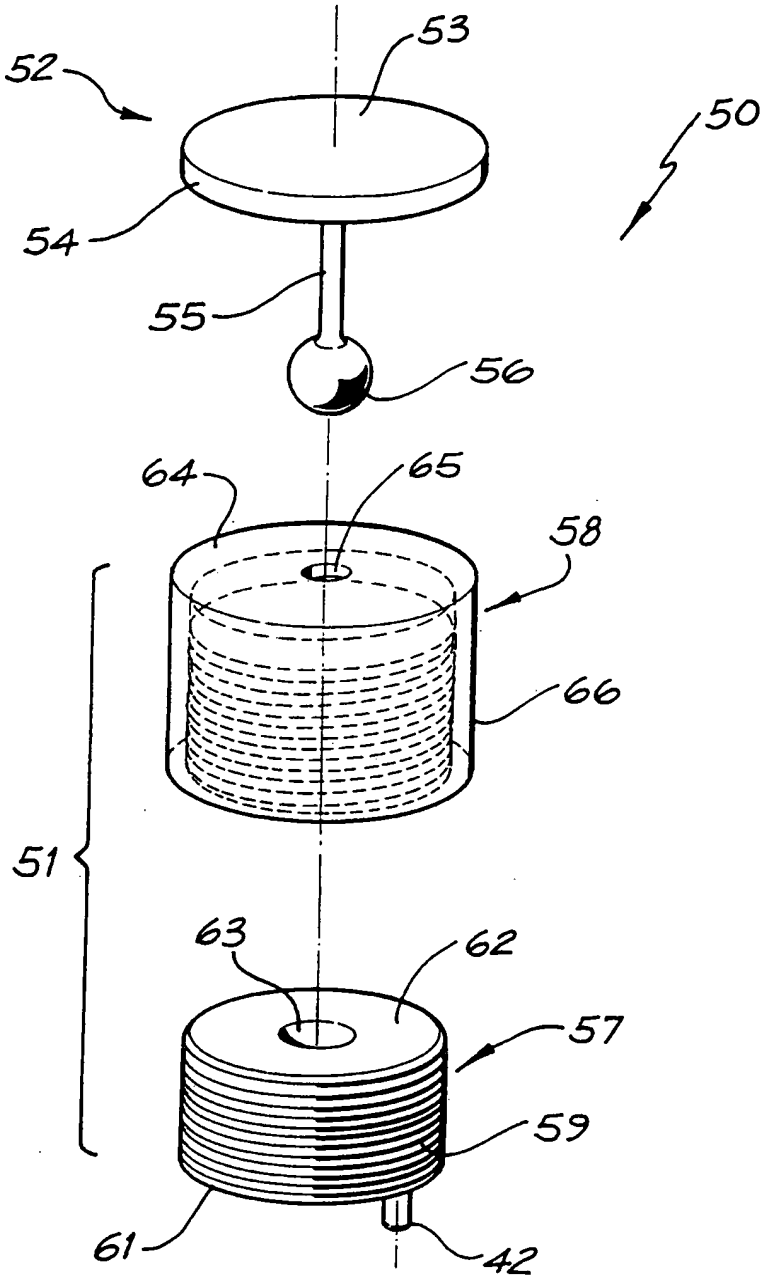

FIG. 3a

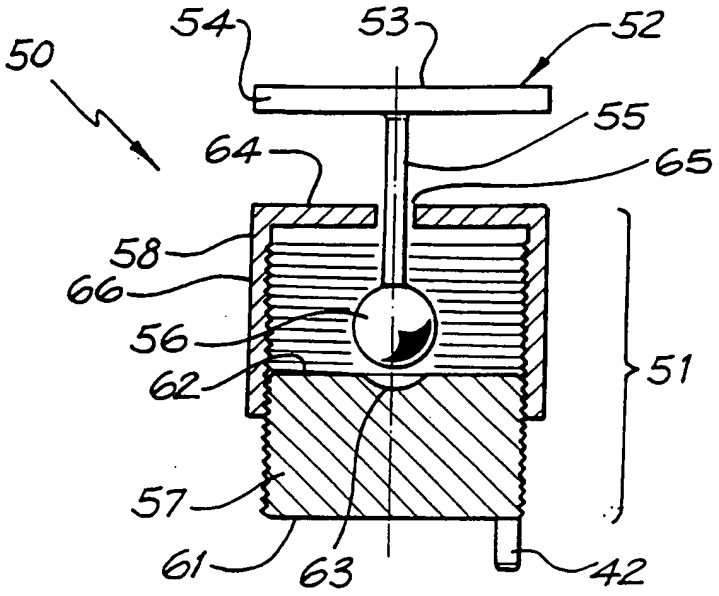

FIG. 3b

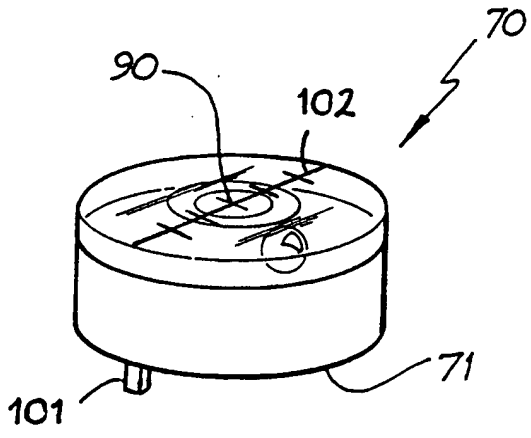

FIG. 4

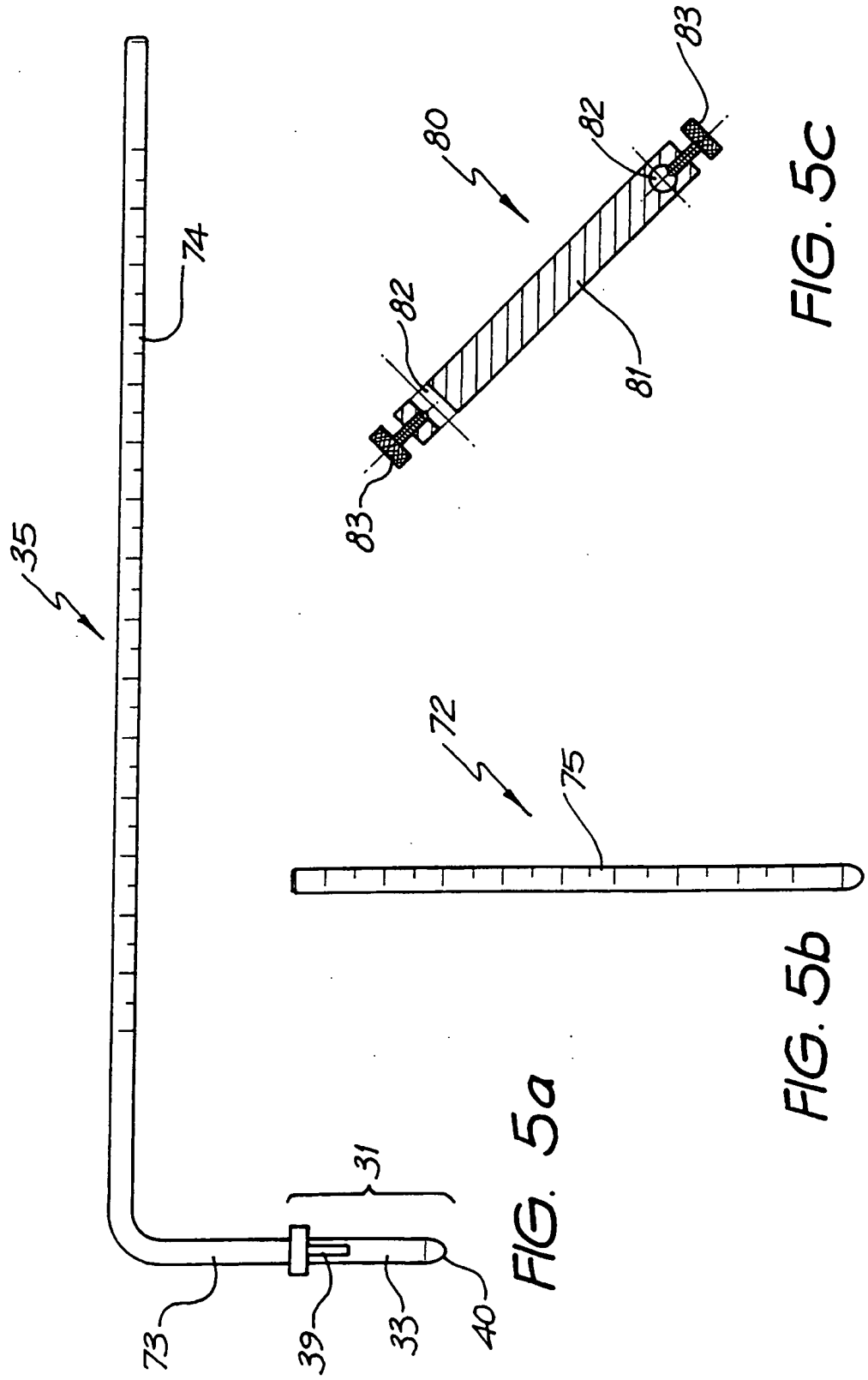

FIG. 5a

FIG. 5b

FIG. 5c

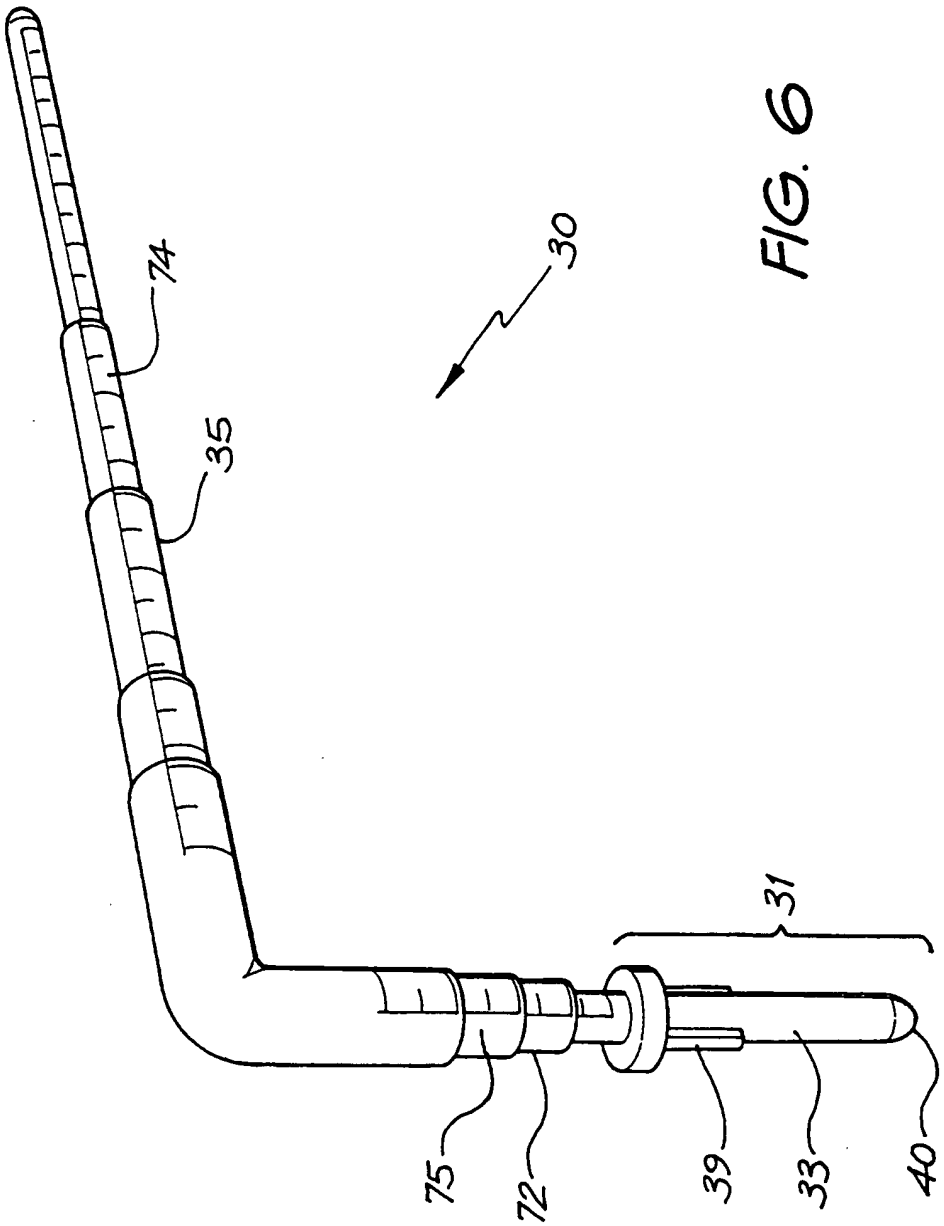

FIG. 6

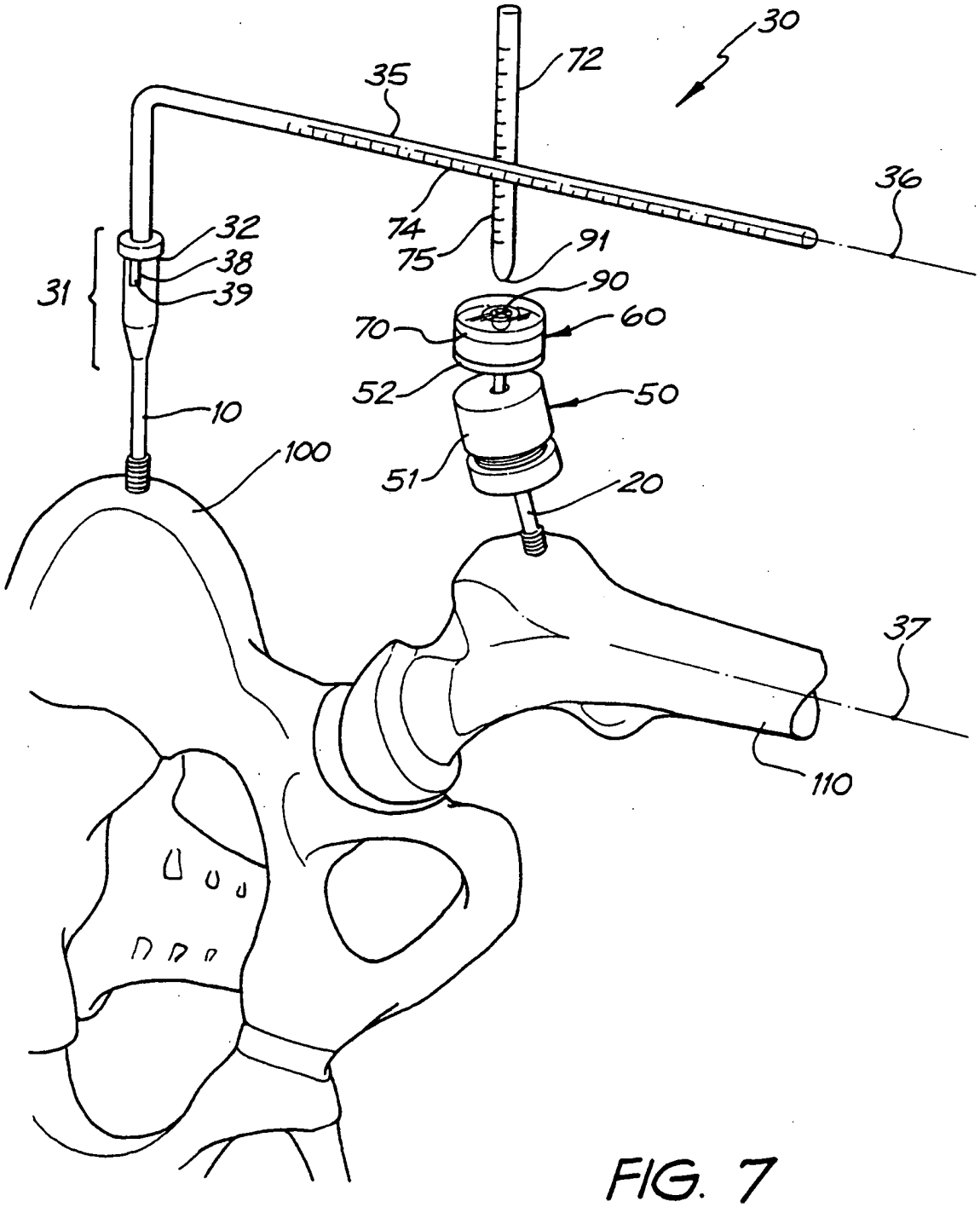

FIG. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU00/01305

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: A61B 17/56

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC A61B 5/-, 17/-, A61F 2/-, G01B, G01C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DWPI + Keywords

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5122145 A (FISHBANE) 16 June 1992	
A	US 5303480 A (CHEK) 19 April 1994	

☐ Further documents are listed in the continuation of Box C ☒ See patent family annex

* Special categories of cited documents:

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
8 November 2000	8 - DEC 2000
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer GEOFF SADLIER Telephone No : (02) 6283 2114

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU00/01305

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member
US	5122145	NONE
US	5303480	NONE

END OF ANNEX